

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

MSP RECOVERY CLAIMS, SERIES LLC, )  
a Delaware entity, MAO-MSO RECOVERY II, )  
LLC, a Delaware entity, and MSPA CLAIMS 1, )  
LLC, a Florida entity, ) No. 18-cv-2211 (BRM) (CLW)  
)  
Plaintiffs, )  
)  
v. )  
) Hearing Date: 12/23/22  
SANOFI-AVENTIS U.S. LLC, )  
NOVO NORDISK INC. and ELI )  
LILLY AND COMPANY, )  
)  
Defendants. )  
\_\_\_\_\_)

**BRIEF IN SUPPORT OF MOTION FOR LEAVE TO FILE  
THIRD AMENDED COMPLAINT AND SUBSTITUTE PLAINTIFF**

Pursuant to Fed. R. Civ. P. 15 and 25(c), and L. Civ. R. 15.1, Plaintiff MSP Recovery Claims, Series LLC, MAO-MSO Recovery II, LLC and MSPA Claims 1, LLC (collectively “Plaintiffs” or “MSP”) hereby move for leave to amend the Second Amended Complaint (the “SAC”) and file a Third Amended Complaint (the “TAC;” attached as **Exhibit A** to Certification of Eduardo E. Bertran with redlined version, as required by L. Civ. R. 15.1(a)(2), attached as **Exhibit B**), and substitute a plaintiff. Defendants oppose the relief.

## **INTRODUCTION**

This is a complex case brought by MSP against the three major U.S. insulin manufacturers: Eli Lilly, Novo Nordisk, and Sanofi Aventis (collectively “Defendants”) for their unlawful and deceptive pricing practices.<sup>1</sup> These practices have led to third party payers not knowing what the actual price of insulin is.

MSP has brought this case on behalf of several third-party payors who have assigned their recovery rights to MSP, including Medicare Advantage Organizations (“MAOs”) and their respective downstream entities such as Medical Services Organizations (“MSOs”) and Independent Physician Associations (“IPAs”).

### *A. What the Proposed TAC Does*

The proposed TAC does the following:

- It streamlines allegations in the SAC in order to conform with the evidence adduced during discovery, including how the rebate scheme works and the damages sought;
- It cleans up the factual allegations in the SAC related specifically to certain causes of actions (RICO, for example) that were dismissed by Court order;
- It incorporates and references significant and topical developments that have occurred since the filing of this case in 2017. Specifically,

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<sup>11</sup> See 16 C.F.R. §§ 233.2-3, 5.

Congress has held multiple hearings into drug prices, featuring these very Defendants as witnesses and resulting in two congressional reports: 1) a congressional report on the overall pharmaceutical market wherein Defendants practices are mentioned among other manufacturers, “*Drug Pricing Investigation: Majority Staff Report*” ; and 2) a United States Senate Report on the insulin drugs at issue in this litigation, “*Insulin: Examining the Factors Driving the Rising Costs of a Century Old Drug.* ” Additionally, in June 2022, the Federal Trade Commission issued a policy statement regarding the insulin pricing scheme (“Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products”).

- It further reduces the number of assignors MSP is bringing the case on behalf of to fifteen assignors:

1. Fallon Community Health;
2. Network Health Plan Inc.;
3. SummaCare Inc.;
4. Health First Health Plans;
5. Group Health Incorporated and Health Insurance Plan of Greater New York Inc. (“Emblem”);
6. Connecticare Inc.;
7. SE Primary Care Services, C.S.P.;
8. AvMed Inc.;
9. Suncoast Medical Network 2, Inc.;
10. Suncoast Provider Network, Inc.;
11. Clinica Las Mercedes, Inc.;

12. Physician Access Urgent Care Group, LLC;  
13. Premier Care Partners, LLC;  
14. Corporacion Medica Oriental; and  
15. Interamerican Medical Center Group, LLC.

- It drops one plaintiff (PMPI) due to the dropping of certain assignors and adds another plaintiff (MSP Claims Series 44, LLC) as a transferee of interest pursuant to F. R. Civ. P. 25(c).

*B. What the Proposed TAC Does Not Do:*

The proposed TAC does **not** do any of the following:

- Add any additional counts or causes of actions;
- Create new theories of liability necessitating additional discovery; or
- Materially prejudice Defendants.

As set forth below, the proposed TAC incorporates recent developments and streamlines the allegations to narrow the issues that will be tried.

**BACKGROUND**

Plaintiffs initially filed this action in the Western District of Texas in 2017. Pursuant to the parties' agreement, Plaintiffs dismissed their case in Texas and refiled in the District of New Jersey in 2018. On March 29, 2019, Judge Martinotti granted Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint as to Plaintiffs' RICO and some state consumer protection counts but denied Defendants' Motion as to a balance of other state consumer protection and common law fraud

claims. Plaintiffs filed their First Amended Complaint on June 28, 2018. On February 20, 2020, Judge Martinotti similarly dismissed Plaintiffs' RICO claim and some state law claims but denied dismissal as to other state law claims. Plaintiffs subsequently filed the Second Amended Complaint on April 29, 2019. The Court entered its order on Defendants' Motion to Dismiss the Second Amended Complaint on February 20, 2020. Pursuant to the Court's Scheduling Order [D.E. 162], the deadline to amend the pleadings was April 20, 2021.

Several important developments have occurred since the filing of the SAC. First, the United States Senate Finance Committee began a years' long investigation into insulin pricing, issuing congressional subpoenas and interviewing several key employees from each of the Defendants here. The Senate's investigation resulted in the United States Senate Finance Committee Report, "*Insulin: Examining the Factors Driving the Rising Costs of a Century Old Drug*" (the "Senate Report"), which was released in 2021 and whose findings have been referenced and incorporated into the proposed TAC. For example: the structure of the insulin delivery and payment pathways create several incentives for entities along these pathways to artificially raise the price of insulin;<sup>2</sup> contrary to Defendants' assertions

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<sup>2</sup> See Congressional Report Diabetes Caucus Co-Chairs Representatives Diana DeGette and Tom Reed, *Insulin: A Lifesaving Drug Too Often Out of Reach*, at 10, available at: <https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes>

about the increased List Prices being the result of research and development, and Defendants spent a modest percentage of revenue on research and development, while providing \$29 billion in stock buybacks and shareholder dividends.<sup>3</sup>

A further development was the issuance earlier this year of the Federal Trade Commission’s policy statement regarding insulin pricing: “Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products” (the “FTC Policy Statement”) which stated, in part:

These rebate and fee agreements may incentivize PBMs and other intermediaries to steer patients to higher-cost drugs over less expensive alternatives. This practice could lead to increased costs for both patients and payers, including increased out-of-pocket costs at the point of sale. It may also insulate more expensive drugs from competing with less expensive alternatives. Nothing prevents drug manufacturers, PBMs, and health plans from negotiating good-faith rebates and fees for legitimate services that increase value to payers and patients. However, when dominant drug manufacturers or intermediaries stifle or foreclose competition from significantly less expensive generic and biosimilar alternatives, the Commission has the legal authority to investigate these practices and take enforcement action against unlawful conduct.

Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products,

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[%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf](#) (last visit October 11, 2022)

<sup>3</sup> See Staff of S. Fin. Comm., , 117<sup>th</sup> Cong., *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, January 14, 2021, available at: [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf) (last visited July 11, 2022) (hereinafter the “Finance Report”).

[https://www.ftc.gov/system/files/ftc\\_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf) at\*4 (last accessed November 3, 2022). Additionally, the Federal Trade Commission announced they will begin investigating the Pharmaceutical Benefit Managers on June 7, 2022. On October 6, 2022, several Senators published a letter outlining that “[t]here is widespread bipartisan support for examining PBMs.”<sup>4</sup>

Another development was that substantive discovery began in the fall of 2021 and is still ongoing today. Collectively, the parties have reviewed and exchanged hundreds of thousands of documents and are on pace to conduct nearly one hundred depositions. Evidence adduced during discovery has helped streamline the allegations made in the proposed TAC. For example, the proposed TAC removes certain allegations regarding kickbacks and rebates that did not apply broadly across all assignors, instead focusing on the issues related with the practice of rebates such that the manufacturers sell a majority of their insulin even today at a substantially different price than the List Price; Defendant Eli Lilly admitted as much in front of

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<sup>4</sup> See October 6, 2022 letter from U.S. Senator Charles E. Grassley, *et al.* to Lina Khan, Chairwoman, Federal Trade Commission; attached as **Exhibit C** to Bertran Cert.

Congress.<sup>5</sup> It was not until this lawsuit was filed, a bevy of Congressional hearings were held with Defendants testifying under oath, multiple Congressional reports, and discovery occurred that anyone in the public including Plaintiffs Assignors would know rebates exceed 70% due to a designed lack of transparency in the system.

Additionally, there have been several developments regarding the assignors at issue in this case and the MSP related entities (plaintiffs here) that took their assignments. For example, there are several assignors for whom which MSP is no longer pursuing claims for; the proposed TAC specifically identifies the remaining assignors for which MSP still is bringing claims on behalf of. Because of that, MSP is dropping one plaintiff (PMPI).

Moreover, since the filing of the SAC, the interests in one of the assignors (Health First Health Plans) was transferred from MSP Recovery Claims, Series LLC to MSP Claims Series 44, LLC. MSP seeks to add this plaintiff pursuant to Fed. R. Civ. P. 25(c) to the case via the proposed TAC.

### **LEGAL STANDARD**

Rule 15 governs leave to amend, which allows a party to amend once as a matter of course within a specified time. Fed R. Civ. P. 15(a)(1). After that period

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<sup>5</sup> See Excerpt of Transcript of House of Representatives Subcommittee on Oversight and Investigations, *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin*, April 10, 2019; p.86; attached as **Exhibit D** to Bertran Cert.

has passed, a party may amend only with written consent of the adverse party or with leave of court. Fed. R. Civ. P. 15(a)(2). Once the period for amendment under Rule 15 has expired, the Court must look to Rule 16 to determine whether there is good cause to extend that Rule 15 deadline. This Motion requires consideration of both Rule 15 and Rule 16.

Rule 16(b)(4) states that “[a] schedule may be modified only for good cause and with the judge’s consent.” A magistrate judge has the discretion to decide what kind of showing the moving party must make to satisfy Rule 16(b)(4)’s good cause requirement. Fed. R. C. P. 15 governs amendments to pleadings. The decision to grant or deny leave to amend is committed to the sound discretion of the Court. *Gay v. Petsock*, 917 F.2d 768, 772 (3d Cir. 1990). Pursuant to Fed. R. Civ. P. 15(a)(2), leave to amend the pleadings is generally granted freely. *See Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962); *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Nevertheless, the Court may deny a motion to amend where there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment.” *Id.* However, where there is an absence of undue delay, bad faith, prejudice or futility, a motion for leave to amend a pleading should be liberally granted. *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

Additionally, it is blackletter law that Plaintiffs' are masters of their complaint and may choose the specific theories of recovery so long as Plaintiff can demonstrate the elements of the causes of action. *See Asirobicon, Inc., f/k/a/ Robicon Corporation v. Rolls-Royce PLC and Rolls-Royce Power Engineering PLC*, No. 03-273, 2003 WL 22071002 at \*7 (W.D. Pa. Sept. 5, 2003); *citing Huff v. Nationwide Ins. Co.*, 167 B.R. 53, 58 (W.D. Pa. 1992) (citation omitted), *aff'd*, 989 F.2d 487 (3d Cir. 1993).

## **LEGAL ARGUMENT**

### **I. Good Cause Exists for Amending the Complaint**

Although the deadline to amend the complaint was on April 20, 2021, good cause exists for amending the complaint now. As discussed above, there have been several developments that have occurred since the filing of the SAC and since the deadline to amend passed. First, at the time of the amendment deadline, substantive discovery in this case had not yet begun. No depositions had taken place and the parties had not even agreed upon a ESI Protocol for Plaintiffs' production. Since then, the parties have engaged in extensive discovery, with hundreds of thousands of documents exchanged and nearly one hundred depositions that have either been taken or are currently scheduled. The proposed TAC streamlines several of Plaintiffs' allegations as a result of what has been adduced in discovery, adding some allegations and revelations obtained through discovery and the Congressional

reports while focusing on the deceptive practices practical effects on Plaintiffs' Assignors. With the benefit of information learned in discovery, Plaintiffs have been able to narrow the scope of their allegations and thus streamline the issues that will need to be tried while still alleging the same general scheme by Defendants. These changes are reflected in the proposed TAC.

## **II. There is No Undue Delay**

Delay alone is not sufficient to deny a request for leave to amend, *see Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d. Cir. 1984), but the moving party "must demonstrate that its delay in seeking to amend is satisfactorily explained." *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotations omitted). Courts will deny a request for leave to amend where delay becomes undue, such as when its accommodation creates an "unwarranted burden on the court...[and] unfair burden on the opposing party." *Adams v. Gould*, 739 F.2d 858 at 868.

Prejudice will be considered "undue" when it rises to such a level that the non-moving party would be "unfairly disadvantaged or deprived of the opportunity to present facts or evidence..." *Harrison*, 133 F.R.D. at 468 (internal quotations omitted). In evaluating the extent of any alleged prejudice, the court looks to the hardship on the non-moving party if the amendment were granted. *Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001). "Specifically, [courts] have considered

whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or theories." *Cureton*, 252 F.3d at 273. The court of appeals has stated that "prejudice to the non-moving party is the touchstone for the denial of...amendment." *See Cornell & Co. v. Occupational Safety and Health Rev. Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978); *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989); *see also Estate of Bloom v. Bank One Corp.*, 2006 WL 8457135 (D.N. J. February 17, 2006) (granting motion for leave to amend finding that even though discovery had recently closed, there was no undue delay so as to warrant denial of the motion in light of the liberal policy permitting amendment of pleadings).

As discussed above, the proposed TAC actually benefits Defendants in that it mirrors the same causes of action that are part of the SAC, and will not require additional discovery, cost, or preparation to defend because there are no new theories; MSP is still alleging the same general scheme by Defendants. The parties are still in discovery and the parties are currently not scheduled for trial and have upcoming 30(b)(6) of Plaintiffs' Assignors. The proposed TAC simply streamlines the allegations, and conforms them to what has been revealed in discovery.

Finally, the amended complaint strikes and modifies certain allegations regarding kickbacks. Specifically, Plaintiffs focus on the usage of rebates and how the effects have led to a substantial number of sales occurring, nowhere near the

AWP of the insulins, thus causing Plaintiffs' Assignors damage, resulting in a more streamlined case.

### **III. There is no undue prejudice to Defendants**

Typically, a motion for leave to amend is considered unduly prejudicial when it is filed after the close of discovery and after a defendant's motion for summary judgment has been filed. *See Estate of Bloom v. Bank One Corp*, Civil No. 03-6108 (FLW), 2006 WL 8457135 at 3 (allowing amendment where no trial date had been set and defendants could secure witnesses.) Here, however, discovery is not closed, and no summary judgment motions have been filed. Defendants are in the midst of deposing Plaintiffs assignors, and have yet to depose a single 30(b)(6) witness. Although the TAC essentially strikes certain allegations, Defendants can still conduct discovery on any of the changes without being unduly burdened. Moreover, because the TAC *removes* certain allegations (specifically regarding the use of kickbacks), the allegations at issue have narrowed. Defendants are not unduly prejudiced as a result.

### **IV. Plaintiffs Have Not Alleged New and Separate Claims.**

A defendant that is "required to defend against new allegations made in amended pleadings does not, by itself, constitute undue prejudice." *Woodson v. 3M Co.*, No. 3:21-cv-50244, 2022 WL 1450385, at \*4 (N.D. Ill. May 9, 2022); *see also Estate of Bloom*, 2006 WL 8457135 at 3 ("Defendants have a heavier burden than

merely claiming prejudice, and must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had Plaintiff amended its complaint at an earlier time.) (internal quotations and citations omitted). A court should deny leave to amend “[o]nly where the prejudice outweighs the moving party’s right to have the case decided on the merits.” *Orlowski v. Dominick’s Finer Foods, Inc.*, 937 F. Supp. 723, 732 (N.D. Ill. 1996). Plaintiffs have not alleged any new and separate claims, rather all Plaintiffs have done is provide more clarity as to how they plan prove the elements of their claims. Plaintiffs’ proposed TAC continues to allege that Defendants have violated various state consumer protection statutes through the same actions; Plaintiffs’ merely add federal regulatory backing as a way to objectively demonstrate Defendants’ wrongdoing.

#### **V. The Proposed Amendment is Not Futile**

A motion to amend is also properly denied where the proposed amendment is futile. An amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." *Harrison Beverage Co. v. Dribeck Imp., Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotation marks and citations omitted). In determining whether an amendment is "insufficient on its face," the Court employs the Rule 12(b)(6) motion to dismiss standard (*see Alvin*, 227 F.3d at 121) and considers only the pleading, exhibits attached to the pleading, matters of public

record and undisputedly authentic documents if the party's claims are based upon same. *See Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). When considering whether a pleading would survive a Rule 12(b)(6) motion, the Court must accept all facts alleged in the pleading as true and draw all reasonable inferences in favor of the party asserting them. *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004). "[D]ismissal is appropriate only if, accepting all of the facts alleged in the [pleading] as true, the p[arty] has failed to plead 'enough facts to state a claim to relief that is plausible on its face[.]'" *Duran v. Equifirst Corp.*, Civil Action No. 2:09-cv-03856, 2010 U.S. Dist. LEXIS 22903, 2010 WL 918444, \*2 (D.N.J. March 12, 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). In other words, the facts alleged must be sufficient to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009).

Plaintiffs' proposed amendment is not futile. The proposed TAC still alleges the same general scheme and still maintains the same causes of action that withstood several motions to dismiss. The proposed TAC notes recent developments regarding the insulin rebate scheme, strikes allegations pertinent to the already dismissed RICO claim, removes/adds other allegations in order to conform to what has been adduced during discovery; and enumerates the assignors still at issue in this case. In

short, the proposed amendment is not futile because it changes nothing substantively about the case.

**VI. The Proposed TAC Drops One Plaintiff and Adds Another Pursuant to Fed. R. Civ. P. 25(c)**

Finally, MSP seeks to amend the complaint in order to reflect changes within the group of Plaintiffs themselves. First, as noted above, MSP has “dropped” certain assignors from this case. As a result, there is one plaintiff, Series PMPI, a designated series of MAO-MSO Recovery II, LLC, that no longer has any claims at issue in this case. The proposed TAC does away with this plaintiff.

Additionally, MSP, through this motion, seeks leave to substitute a real party in interest, MSP Recovery Series 44, LLC, as an additional plaintiff in this action. Fed. R. Civ. P. 25(c) states:

Transfer of Interest. If an interest is transferred, the action may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party. The motion must be served as provided in Rule 25(a)(3).

Rule 25(c) speaks to the situation in which there is “any transfer of interest” during the pendency of an action, and the Court may grant substitution in its discretion. Therefore, Rule 25(c) is an appropriate mechanism under which a plaintiff may seek to amend its pleading to substitute a successor as the real party in interest. As alleged in the Complaint, effective April 28, 2016, Health First Health Plans, Inc. (“HFHP”) assigned recovery rights to MSP Recovery, which, on June 12,

2017, further assigned said rights to Series 16-05-456, a designated series of MSPRC. [ECF No. 7, Appx. 2, ¶¶ 72-73]. On October 22, 2020, Series 16-05-456 further assigned all rights assigned to it by HFHP to Series 44-20-456, a designated series of Series 44.

Although not required, MSP desires to add Series 44 as a named Plaintiff in this case. Nor will the substitution prejudice Defendants, as these assignment documents have already been produced and no depositions of any of Plaintiffs have occurred yet.

### **CONCLUSION**

Based on all of the foregoing, MSP respectfully requests that this court enter an order granting this motion, allowing MSP to file a third amended complaint and add an additional plaintiff to reflect a transfer of interest pursuant to Fed. R. Civ. P. 25(c).

Respectfully submitted,

By: /s/ Glenn R. Reiser  
Glenn R. Reiser

Dated: November 23, 2022

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